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10/533,749	05/10/2005	Lawrence Allan Lynn		7983

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Sleep and Breathing Research Institute
Suite 10
1275 Olentangy RR
Columbus, OH 43212

EXAMINER

MEHTA, BHISMA

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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12/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/533,749

Applicant(s)

LYNN, LAWRENCE ALLAN

Examiner

Bhisma Mehta

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/20/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 September 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 09/10/2007.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings were received on September 10 2007. These drawings are acceptable. However, the objections to the drawings as detailed below have not been overcome.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 208. It appears that reference numeral 280 in Figure 5 may need to be changed to be 208 as it does not appear that reference numeral 280 is used in the description. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 270. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in

compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:
 - a. There is a grammatical error in lines 21-24 of page 15.
 - b. The use of "100s" in line 12 of page 15 appears to be an error.
 - c. In lines 18 and 23 of page 16, "404" should be "403".
 - d. In line 10 of page 17, it appears that 'catheter 410" should be "catheter hub 410".

Appropriate correction is required.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the system having a single extension tube. The specification also fails to disclose the method with the steps of reducing the internal volume of the extension tube after a first delay, a second delay,

and a third delay where the first residual fluid is less than the initial volume, the second residual fluid is less than the first residual volume, and the third residual fluid is less than the second residual volume, and the method of maintaining the patency of a lumen of an indwelling catheter over a 24-72 hours period.

Claim Objections

6. Claims 8-34 are objected to because of the following informalities: There appears to be grammatical errors with the following: "said the internal space" in line 12 of claim 8, "said the internal system" in lines 14-15, and "said the terminal" in line 18. In claim 18, it is unclear if the "at least one element" in line 3 is referring to the "at least one volume reducing element" in line 14 of claim 8 or a different at least one element. There appears to be a word missing in the phrase "having distal portion" in line 2 of claim 19. The language in lines 5-7 of claim 27 is unclear as to what is being claimed. In claim 30, it is unclear if the "at least one terminal" in lines 9-10 is referring to the "at least one proximal terminal" in line 8 of claim 30 or a different at least one terminal. There appears to be a punctuation error in the phrase "beneath the skin of a patient the lumen extending into a blood vessel" in line 4 of claim 31. In claim 32, there appears to be a grammatical error in the phrase "after a first delay of a least several hours" in line 7 and the phrase "reducing the internal volume the extension tube" in lines 12-13 and in lines 17-18.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 5-11, 14-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Ash (U.S. Patent No. 6,958,049). Ash discloses a catheter-flushing system having a tubing system comprising a single extension tube (14) and a volume reducer (20). The single extension tube (14) is in fluid connection with an indwelling portion of a catheter (10). In lines 9-28 of column 6, Ash discloses that the tubing system or catheters can include single or double lumens. The tubing system defines an internal volume and at least one proximal terminal including a seal (28). The proximal terminal has intermittent connection with an external fluid source or a flush solution such as saline (lines 14-16 of column 5) or a mixture of a diluent and at least one of an anticoagulant and an antimicrobial agent (lines 25-36 of column 7). Activation of the volume reducer reduces

the volume within the tubing system by a plurality of discrete volumes. As to claim 8, the system includes a single extension tube (14) having a distal end connectable to a catheter (10), an internal open space defining a variable internal volume, and a lumen extending through the tube. The volume reducer comprises at least one volume reducing element (20) mounted within the system where the element comprise a clamp. The volume reducer can be considered to be a pinch clamp and also defines opposing elongated opposing surfaces. The tube (14) has a variable internal diameter (see lines 16-18 of column 6) and includes an enlarged portion as seen in Figure 1. As to claim 19, the fluid-lock system has a distal portion which defines an indwelling portion and a single extension tube (14) having an internal space defining an internal volume. The volume reducer (20) is for engaging the system and for progressively reducing the volume of flush solution contained within the internal space by facilitating movement of at least sequential portions of the flush solution into a blood vessel. As to claims 27 and 29, the system includes a reservoir comprising a single extension tube (14) and a volume reducer (20) configured for engaging sequential portions of the reservoir. As to claim 30, Ash discloses disposing the tubing system comprising a single extension tube (14) in fluid connection with an indwelling portion of a catheter (10), flowing flush solution from an external fluid source, sealing the proximal terminal of the tubing system, and progressively reducing the internal volume of the tubing system through the use of a volume reducer. As to claim 31, Ash discloses disposing a single extension tube (14) in fluid connection with an indwelling portion of a catheter (10), flowing flush solution from an external fluid source, sealing the proximal terminal of the tubing

system, and sequentially reducing the internal volume of the extension tube a plurality of different times to displace sequential portions of the residual volume of the flush solution into the lumen through the use of a volume reducer (line 61 of column 4 to line 21 of column 5 and lines 45-62 of column 5). As to claims 32-34, Ash also discloses first, second, and third delays of at least several hours where after each delay, the internal volume of the extension tube is reduced to force flush solution distally out of the extension tube and along the lumen (line 61 of column 4 to line 21 of column 5 and lines 45-62 of column 5). As to claims 35 and 36, Ash discloses a method for maintaining the patency of a lumen of an indwelling catheter over a 24-72 hour period where the internal volume of the extension tube is reduced a plurality of times to express sequential portions of the flush solution from the extension tube into the lumen to sequentially flush the lumen at a plurality of different times (line 61 of column 4 to line 21 of column 5 and lines 45-62 of column 5).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash in view of Rath et al. Ash discloses the system substantially as claimed. However, Ash is silent on the volume reducer comprising a plurality of clamps. Rath et

al disclose a single extension tube (12) with a volume reducer (16) comprising a plurality of clamps (46, 48) where the volume reducer is used to prevent unwanted fluid leak. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the volume reducer of Ash with the volume reducer having a plurality of clamps as taught by Rath et al as a mere substitution of one type of volume reducer for another.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1, 5-26, 29, and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-9, 11-30, 32, 33, and 35 of U.S. Patent No. 6,689,109. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the claims are all drawn to a system or method for maintaining the patency of a lumen of a catheter or for flushing a lumen of a catheter.

Response to Arguments

12. Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection.

Terminal Disclaimer

13. The terminal disclaimer filed on September 10 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,689,109 has been reviewed and is NOT accepted. The assignee has not established its ownership interest in the patent, in order to support the terminal disclaimer. There is no submission in the record establishing the ownership interest by either (a) providing documentary evidence of a chain of title from the original inventor(s) to the assignee and a statement affirming that the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11, or (b) specifying (by reel and frame number) where such documentary evidence is recorded in the Office (37 CFR 3.73(b)).

The disclaimer fee of \$65 in accordance with 37 CFR 1.20(d) has not been submitted, nor is there any authorization in the application file to charge a specified Deposit Account or credit card.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

KEVIN C. SIMONS
SUPERVISORY PATENT EXAMINER

